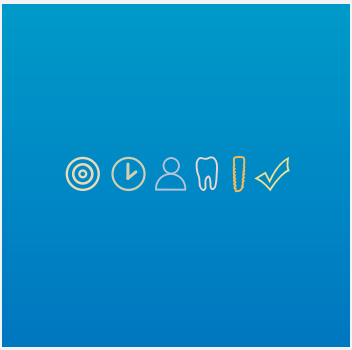
MIS®

User Manual



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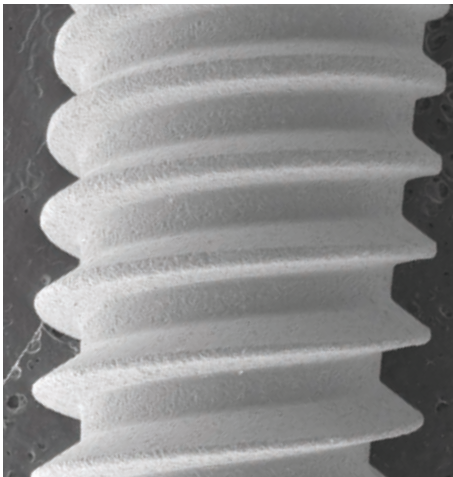
Note: This User Manual is for educational purposes only.

The MIS Quality System complies with international quality standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 – Quality Management System and CE Directive for Medical Devices 93/42/EEC. MIS products are cleared for marketing in the USA and CE approved.



Overview.

8. Introduction
9. Raw Material
12. Manufacturing Process
13. Implant Surface
16. Histology
17. Hydrophilicity

Overview
Introduction

MIS is a dynamic, state-of-the-art production company, developing and manufacturing a comprehensive range of dental implants designed to provide long-lasting successful solutions to partial and complete edentulous conditions. MIS implant systems combine several advantageous elements such as choice of raw materials, macro-structure, micro-structure and surface treatments, in order to achieve high primary stability and successful osseointegration.

MIS upholds high quality standards by conducting comprehensive quality assurance evaluations throughout the entire production process. The unique MIS implant surface treatment combines sand-blasting and acid-etching to increase surface area, creating both micro and nano-structures and eliminating surface contaminants. The implant surface is continuously monitored by a comprehensive series of tests, conducted both in-house and by internationally recognized research institutes.
Tests include:

- Mechanical tests
- XPS analysis
- Roughness analysis
- Surface analysis
- SEM evauations
- Cytotoxicity tests
- Sterility validations
- Torque removal values
- Histology

Overview

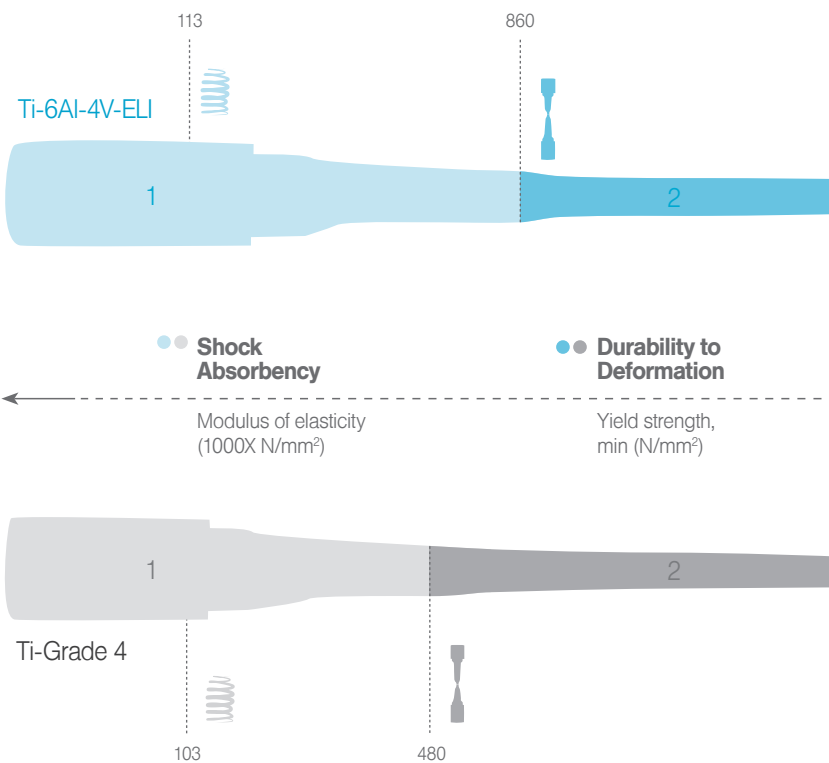
Raw Material

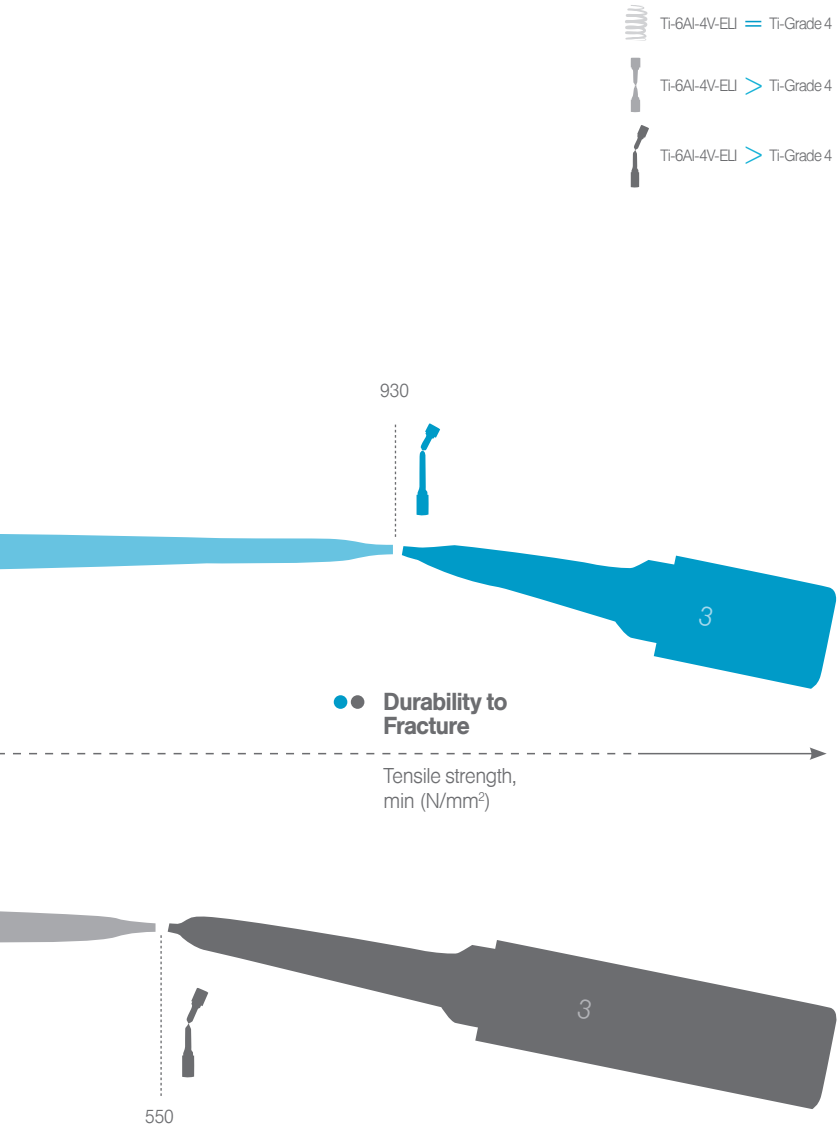
- Biocompatible
- Safe
- Long-term proven clinical success
- Superior mechanical properties

All MIS implants are made from Ti-6Al-4V ELI (Grade 23), the higher purity version of Ti-6Al-4V. This specific type of alloy combines biocompatibility, excellent fatigue strength and low elastic modulus. These benefits make Ti-6Al-4V ELI mechanically superior to titanium grade 4 and the ultimate dental and medical titanium grade.

Similar to commercially pure titanium (Grades 1-4), the outer surface of all MIS implants are comprised of a thin layer of pure titanium oxide (TiO_2). In this way, bone cells cannot differentiate between the different titanium grades. The TiO_2 layer also prevents metallic ions leaking from the alloy, for safe long-term use.

Mechanical Properties
Raw Material




Ti-6Al-4V-ELI = Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4
Ti-6Al-4V-ELI > Ti-Grade 4
930
3
Durability to Fracture
Tensile strength, min (N/mm²)
3
550

Overview

Manufacturing Process

Structure (Raw Material)

MIS Surface Treatment

Sand-Blasting

Acid-Etching

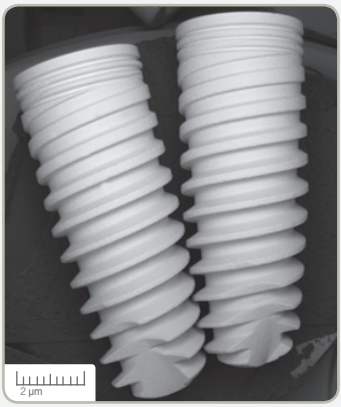
Roughness (Macro and Nano Structures)

The combination of sand-blasting and acid-etching induces macro and nano-structures that significantly increase surface area of the implant body for optimal osseointegration. The roughened surface improves bone adhesion, as well as the proliferation and differentiation of osteoblasts.

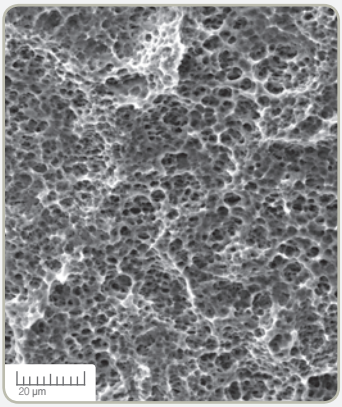
Overview

Implant Surface

Osseointegration is defined as the attachment of bone to dental implants, and is the critical factor related to the long-term success of dental implants. Osseointegration is determined by both the raw material of the implant, morphology and surface chemical composition.



SEM image of two C1 implants



SEM image of the implant surface

Macro-structure

The geometric design of the body and thread profile of the implant act to increase primary stability and to distribute forces from the implant to the surrounding bone.

Micro and nano-structure

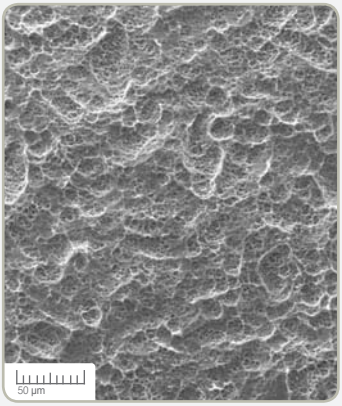
All MIS implants are sand-blasted and acid-etched. This surface treatment increases the implant surface area, creating both micro and nano-structures, while eliminating various surface contaminants.

MIS is one of only a handful of companies worldwide using electron microscopy on a daily basis for implant quality inspection.

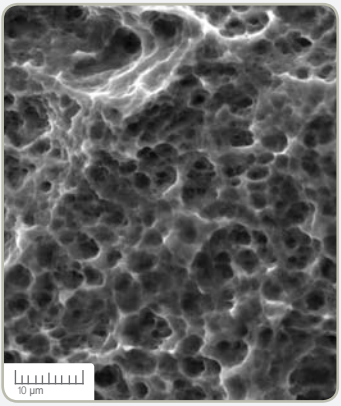
Sand-blasted and acid-etched surfaces have been substantially proven to maximize the BIC (Bone-to-Implant Contact), achieving immediate and long-lasting osseointegration.

Surface composition

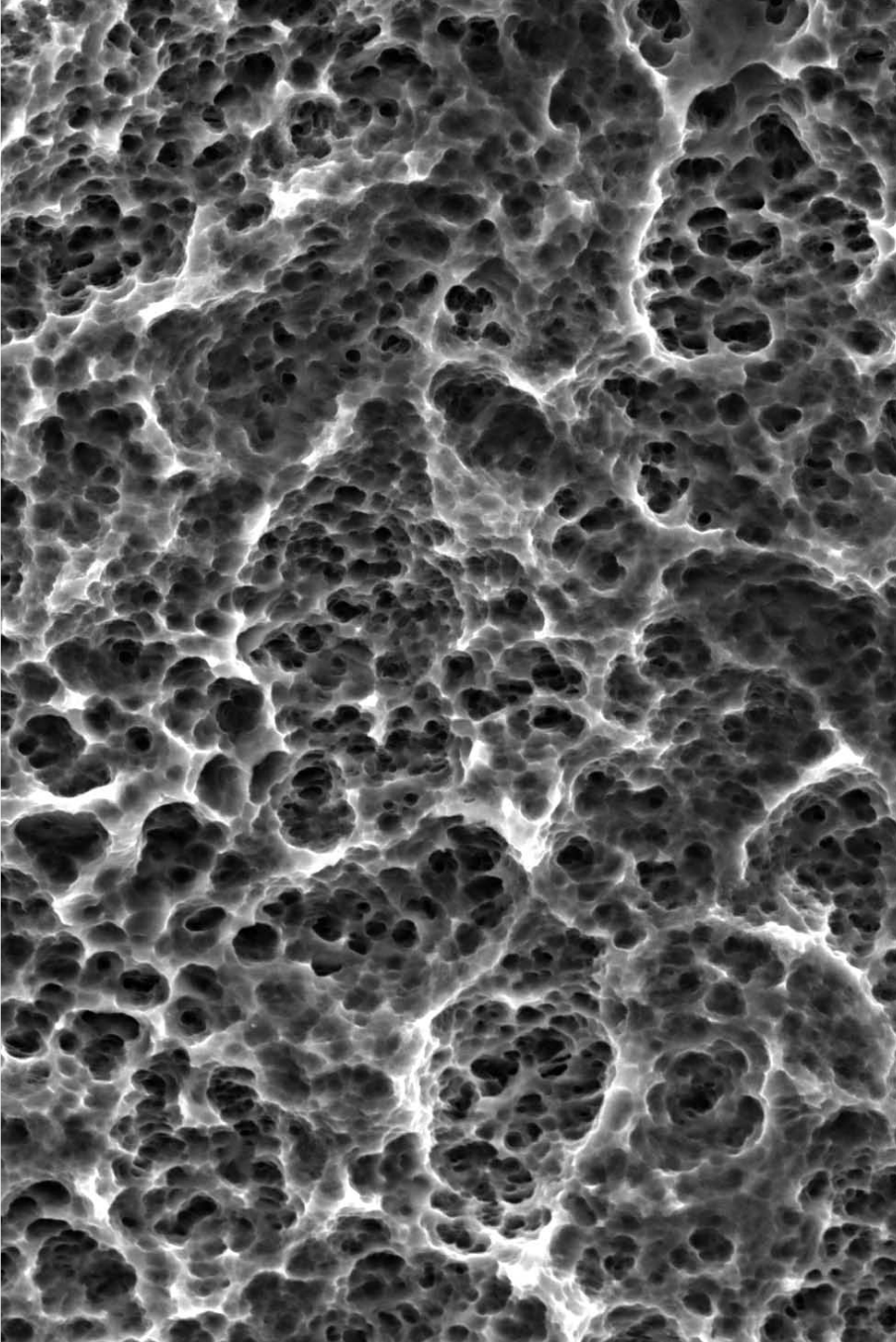
The outer surface of MIS implants, consist of a thin layer of pure titanium oxide (TiO2). Acid-etching and packaging processes are performed in a controlled environment clean-room to ensure purity and quality. Implants are inspected by electron microscope (SEM) scan and X-ray photoelectron spectroscopy (XPS), to ensure implants are free of contaminants.



SEM image of the implant surface showing the micro-structure

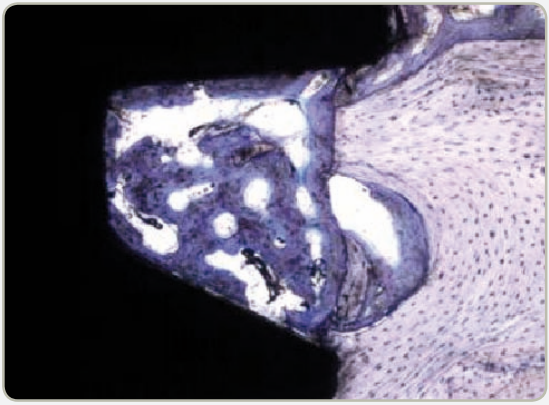


SEM image of the implant surface showing the nano-structure



Overview
Histology

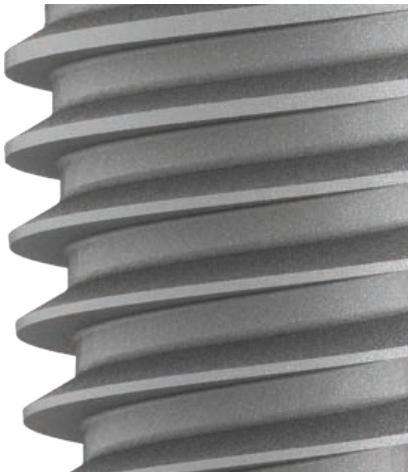
Histologic section of a C1 implant, 5 weeks after placement.
Courtesy of Paulo G. Coelho, DDS, PhD, NYU College of Dentistry.



Histologic section of a C1 implant, 5 weeks after placement. Courtesy of Paulo G. Coelho, DDS, PhD, NYU College of Dentistry

Overview
Hydrophilicity

Current literature demonstrates a linkage between improved bone healing and early osseointegration with the hydrophilicity of surface. MIS implant surface treatment combines sand-blasting and acid-etching. This combination ensures surface purity and hydrophilic properties. The images demonstrate liquid "climbing" upwards on the implant surface.



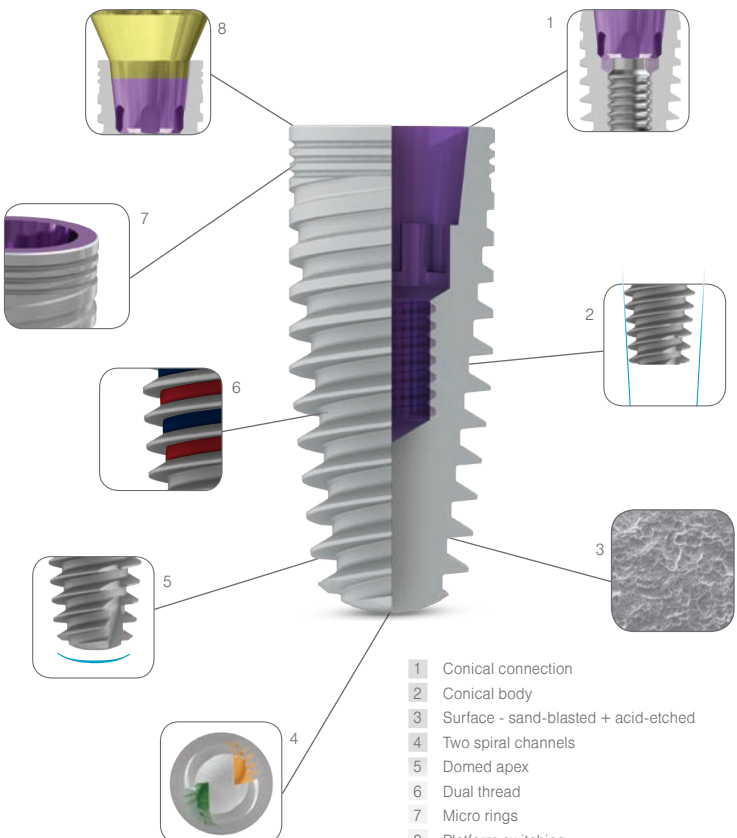
Implants.

20. Introduction: C1 Implant
21. Fixture - Technical Info
23. Features
24. Implant Range
25. Procedure

C1
Introduction

MIS is proud to introduce C1, an addition to our implant selection. The C1 implants feature a unique combination of attributes that result in a new innovative implant that provides high initial stability and a state of the art conical connection which incorporates platform switching technology. A large variety of superstructures and components are available, providing solutions for every possible clinical scenario. All implants and components are color-coded, according to their restorative platform, with a golden anodized hue for best esthetic results.

C1
Fixture - Technical Info



1 Conical connection
2 Conical body
3 Surface - sand-blasted + acid-etched
4 Two spiral channels
5 Domed apex
6 Dual thread
7 Micro rings
8 Platform switching

C1
External Design

Platform switching

The C1 features platform switching, that keeps the implant-abutment connection away from the bone; minimizing bone resorption. Platform-switching additionally allows more vital growth of the soft tissue.

Conical shape

- The conical root shape of the C1 implant and a unique thread design ensure superior primary stability, making the C1 the implant of choice for a wide range of clinical cases and loading protocols.
- The root shape design makes the C1 an ideal implant when space is restricted due to adjacent teeth or implants.

Two spiral channels and domed apex

The C1 features a domed apex, providing a high tolerance and safe procedure during insertion. Two cutting blades at the implant apex establish the self-tapping properties of the C1; supporting a simpler, safer and faster procedure.

Dual thread

- The C1 features a dual thread design which increases the BIC (Bone to Implant Contact) over the entire body of the implant. The dual thread doubles implant insertion rate (1.50mm), facilitating a simpler and faster implant placement.
- The thread profile is especially designed for a flawless, easy insertion and a high primary stability.
- The C1 is self taping with mild bone compression that enhances primary stability.

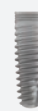
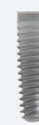
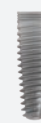
Surface treatments

C1 implants are sand-blasted and acid-etched. These surface treatments increase the implant surface area by creating both micro and nano-structures and eliminating various surface contaminants.

Micro-rings

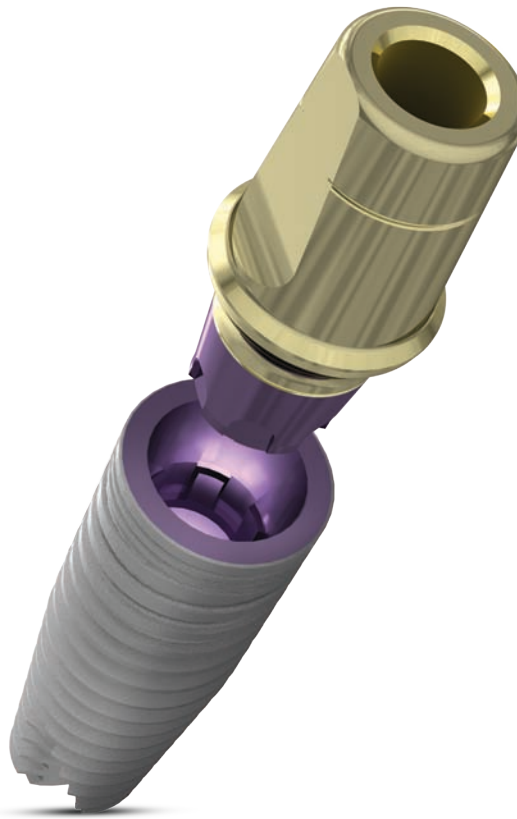
At the neck of the C1, micro-rings significantly increase the BIC (Bone to Implant Contact), avoiding bone resorption at the crestal zone.

C1
Implant Range

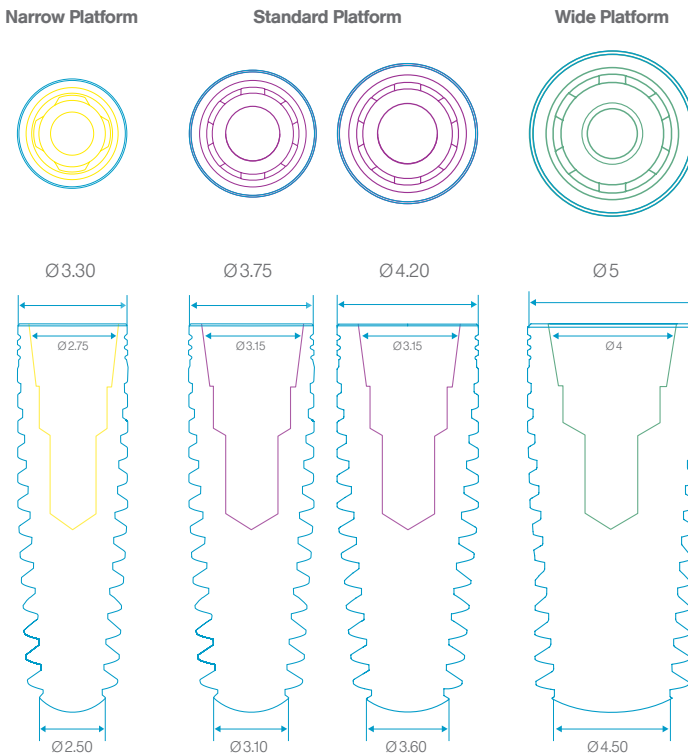
Length	8mm	10mm	11.50mm	13mm	16mm
Type					
Ø3.30mm Screw type implant Narrow platform		C1-10330	C1-11330	C1-13330	C1-16330
Ø3.75mm Screw type implant Standard platform	C1-08375	C1-10375	C1-11375 	C1-13375 	C1-16375
Ø4.20mm Screw type implant Standard platform	C1-08420	C1-10420	C1-11420	C1-13420 	C1-16420
Ø5mm Screw type implant Wide platform	C1-08500	C1-10500	C1-11500	C1-13500	C1-16500

* Implant package includes: a cover screw, a temporary cylinder and a final drill.

C1
Conical Connection



The C1 features a 6-degree conical connection to ensure a secure fit between the abutment and implant. By minimizing micro-movement at that junction bone loss at the crestal level is reduced. There is a six-position cone index within the conical connection to help orient the implant during insertion as well as placing the abutment into the proper position.

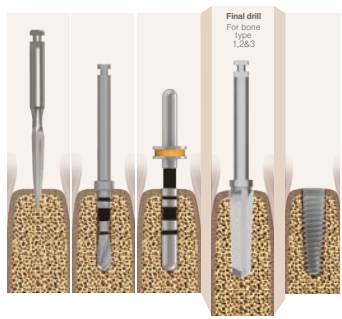


C1
Ø3.30mm / Ø3.75mm Procedure

Recommended insertion torque: 35-60 Ncm.

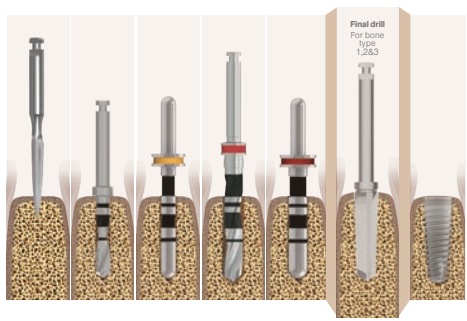
ø3.30mm

Drill Speed (RPM)	1200-1500	900-1200			200-400	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3	Ø3.60	Ø3.30



ø3.75mm

Drill Speed (RPM)	1200-1500	900-1200		500-700		200-400	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3	Ø3	Ø3 Ø3.60	Ø3.75



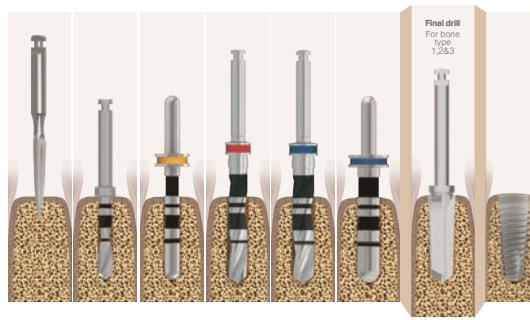
- Do not use the final drill for type 4 bone.
- The drilling sequence is demonstrated using a 13mm implant.
- Procedure recommended by MIS cannot replace the judgment and professional experience of the surgeon.

⊂1
Ø4.20mm / Ø5mm Procedure

Recommended insertion torque: 35-60 Ncm.

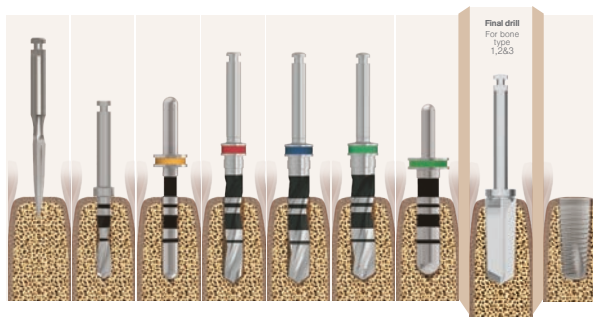
Ø4.20mm

Drill Speed (RPM)	1200-1500	900-1200		500-700	400-700		200-400	
							Ø3.50	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3	Ø3.50	Ø3.50	Ø4	Ø4.20



Ø5mm

Drill Speed (RPM)	1200-1500	900-1200		500-700	400-700	400-600		200-400	
								Ø4.10	15-25
Diameter	Ø1.90	Ø2.40	Ø2.40	Ø3	Ø3.50	Ø4	Ø4	Ø4.90	Ø5



Surgical Procedures.

For MIS Implants

28. Indications & Contraindications
30. Step-by-Step Protocol

Surgical Procedures
Indications & Contraindications

Indications

Adequate bone is needed to support the implant with width and height being the primary dimensions of concern. The amount of available bone should be evaluated based on accepted imaging and radiological techniques used in implant dentistry.

In addition, a very careful evaluation must be made as to the location of vital blood vessels, nerves, maxillary sinus, soft tissue spaces, and their relation to the site planned for implant placement.

Contraindications

All contraindications associated with elective surgery should be considered.

These include, but are not limited to:

- Metabolic bone diseases.
- Blood and clotting disorders.
- Medications affecting clotting or bone turnover.
- Significant vascular or anatomic factors at the implant site.
- Treatments, medications, or disorders that interfere with bone biology or wound healing.
- Hypersensitivity or known allergy to any components of the implants or their superstructures.

Other Contraindications

- Poor patient motivation.
- Psychiatric disorders that interfere with patient understanding and compliance with the necessary procedure.
- Unrealistic patient expectations.
- Unattainable prosthodontic reconstruction.
- Inability of patient to manage oral hygiene.

Risks

Risks associated with the surgical procedure fall into four broad categories:

1. Immediate anesthetic and surgical risks.
2. Psychological and psychiatric risks.
3. Medical threats to long-term retention.
4. Long-term deleterious effects of implants on health.

The risks may include:

Inadvertent perforation of the nasal maxillary sinus, local and systemic infections, perforation into soft tissue spaces, rupture of primary blood vessels and nerve injury.

Temporary conditions that might result from implant placement may include pain and swelling, speech difficulties and haemorrhage.

Long-term complications may include (but are not limited to) nerve injuries and persistent

local or systemic infections. Special care and attention needs to be given to susceptible individuals with compromised immune systems due to medications, systemic conditions or those who underwent body-part replacements.

Important Warning

Practitioner's lack of adaquate training, knowledge and experience are considered major risk factors to the patient's health and to implant success. Therefore, no implant placement procedure should be performed without prior training by a certified institution.

Surgical Procedures

Step-by-Step Protocol

The surgical manual is designed to provide an overview of the pre-surgical and the surgical procedures applicable to the C1 implant range. Successful implant placement procedures are the result of a wide range of factors. This step-by-step protocol aims to ensure that significant factors are not overlooked.

Step 1.
Patient Selection and Medical History
(General medical history)

Patients must be carefully assessed for their ability to safely undergo surgical procedures. Medical history should be evaluated to ensure that patients are not put at risk. Certain medical conditions are considered either absolute or relative contra-indications for surgery. These may relate (but not be limited) to the following conditions: Patients who are either taking or have taken medications for the treatment of osteoporosis; immunodeficiency or immunosuppressive treatments; malignancies; head and neck radiation; poorly controlled diabetes or other hormonal disorders; bleeding disorders or anticoagulant therapy; recent myocardial infarction, severe cardiac insufficiency and valve pathology; general bone diseases; hypersensitivity or known allergy to specific relevant materials; psychiatric or personality disorders that limit or interfere with patients' understanding and compliance. Please be aware of the fact that updates based on current medical literature may include or exclude certain conditions.

Step 2.
Dental Conditions and Oral Hygiene

A complete and thorough intraoral examination must be performed and recorded. This must include an evaluation of the dentition, oral hygiene, smoking, habits, attitude to oral health, and any other relevant information. Implant procedures should not be performed on patients with active osteolitic conditions, active periodontal disease or infectious areas at the implant site. Extreme bruxing and clenching should be taken into consideration.

Step 3.
Radiographs and Imaging

Diagnosis and treatment planning for implant placement require the use of different types of radiographs and imaging technologies. Panoramic radiographs are considered standard pre-surgery radiographs, however additional imaging modalities such as CT (Computerized Tomography), tomography and periapical radiographs may be required.

It should be emphasized that certain countries require specific radiographs to be taken before, during and after surgery. It is the obligation of the surgeon to ensure that all required documentation is available and recorded before and after surgery. Vertical and horizontal dimensions of implant sites should be measured and charted. The anatomical relationships of neighboring teeth and proximity to anatomical structures such as the mandibular canal, maxillary sinus and base of the nose must be evaluated. Bone inclination and shape should also be taken into account. Surgical guides with radiopaque markers are recommended. These, coupled with computerized tomographic radiographs can later be altered to be used as computer based surgical guides.

Step 4.
Treatment Plan
(Patient cooperation)

Based on patients' needs, alternative treatment plans should be considered and discussed. The chosen treatment plan should result in a sequence of actions related to initial preparations, surgical phase and a restorative phase.

Surgical Procedures

Step-by-Step Protocol

Step 5A.
Implant Selection

C1 implants feature a range of diameters and lengths. It is recommended that Wide platform implants are used in the premolar and molar areas, while Standard platform implants are used in the anterior areas. Specific analysis of available bone and distance from vital structures at each proposed site may lead to the choice of specific implant length and diameter; however, current augmentation procedures may allow the use of longer or wider implants.

Step 5B.
Surgical Phase

Surgery should be performed under strict infection control conditions. Preoperative medications and/or antibiotics may be required based on the patient's condition and the extent of surgery, and should be decided upon by the operating surgeon. Other monitoring measures, including blood-pressure and pulse measurements should also be considered. Emergency resuscitation apparatus should be available.

Warnings: C1 implants are supplied in a sealed and sterilized package. Implants should never be reused, and implants whose sterility is compromised should not be used. Implants should not be used later than the specific expiration date printed on the package. Implant placement should be performed in accordance with acceptable placement and loading protocols. MIS recommended procedures are described on pages 20-43. However, it should be emphasized, that procedures recommended by MIS cannot replace the judgment and professional experience of the surgeon.

The sale of MIS implants is restricted by law to licensed dentists only. Implant placement procedures should only be performed by trained and licensed dentists. Initial planning is of the utmost importance. As this is a prosthetic driven procedure. It is advisable that restorative dentists are involved at the planning and surgical phases as active participants when making decisions affecting the choice of implant type and the 3-dimensional positioning of the implants.

12
24

Step 6.
Osseointegration Phase

Current literature supports multiple loading options. The dentist should decide when to load implants based on specific parameters, related to their individual case.

Step 7.
Restorative Phase

C1 implants can support different types of final restorations. Following the solution specified in the treatment plan, the final restoration is fabricated based on accepted restorative protocols. Special attention should be given to ensure correct occlusal adjustment, in order to prevent overloading the implant. MIS superstructures and components must be used with all MIS implants.

Step 8.
Follow-up

Periodic follow-up evaluations including radiographs are recommended. Special attention should be put on oral hygiene and habits, occlusion adjustments and the stability of the prosthesis.

BODY TRY-IN
Ø5
13
16
HAND WRENCH
DRILL TENDER

Surgical Kits.

36. Surgical Kit Description
38. Advanced Surgical Instrument Kit
40. Kit Contents

The Surgical Kit

Surgical Kit Description

The C1 innovative surgical kit is designed for simple and safe implant placement procedures. The kit introduces a novel ergonomic design that follows the surgical drilling sequence. In addition, the kit includes a set of length-based pilot drills and color-coded visual cues of both implant diameter and restorative platforms.

MK-0044, C1 Surgical Instruments Kit

Please Note:

- The surgical kit is made of medically approved materials.
- The surgical kit can be fully sterilized using an autoclave at 134˚C (273˚F) for 6 minutes. Do not exceed 134°C.
- The surgical kit is compact and easy to store.
- Tray can be removed from the box for easy cleaning and sterilization.
- Steam flow is optimized through built-in vents.

Warning

Avoid damage!

Temperatures higher than 150°C may cause damage. Radel, steel and silicone components may support repeated exposures to temperatures up to 180°C, but the lifetime of the trays may be shortened.

The use of inappropriate chemical agents may cause damage to the trays and to the instruments. Please handle them with care to avoid breakage. Never use broken trays or instruments.

Do not open the box while still hot after sterilization.

Cleaning Procedure

Stainless steel instruments should be cleaned and sterilized with materials that are specifically indicated for these materials. To avoid damage, please refrain from using:

▪ Cleaning and disinfection agents containing high rates of chlorine ▪ Cleaning or disinfection agents containing oxalic acid.

In order to prevent damage to instruments that are color-coded, please refrain from using:

▪ Detergents and cleaning agents containing high rates of the aforementioned chemicals. ▪ Extremely high temperature during cleaning and sterilization.

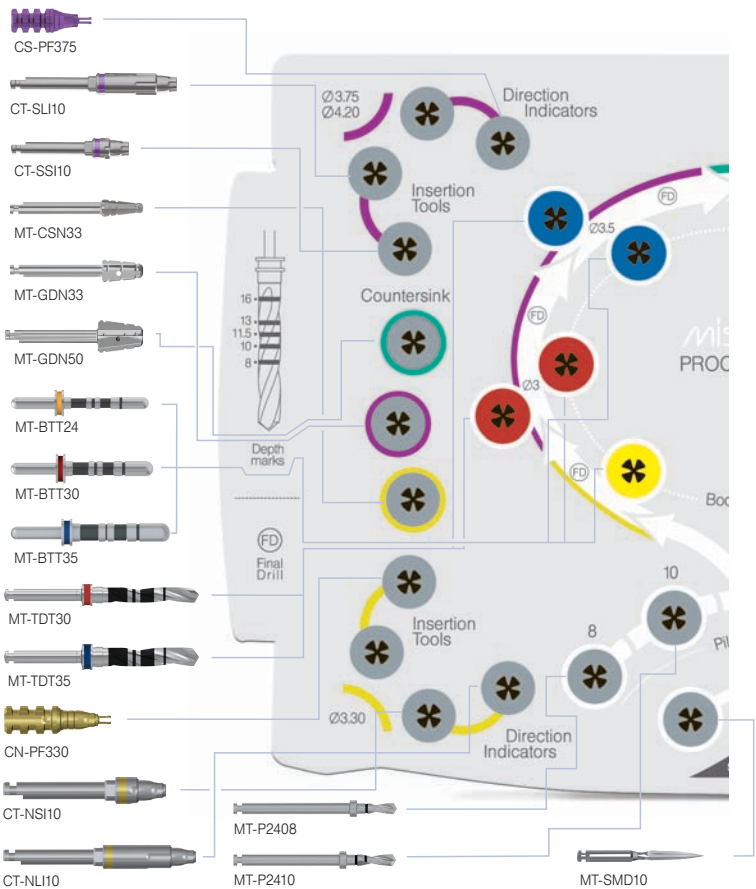
Please Note:

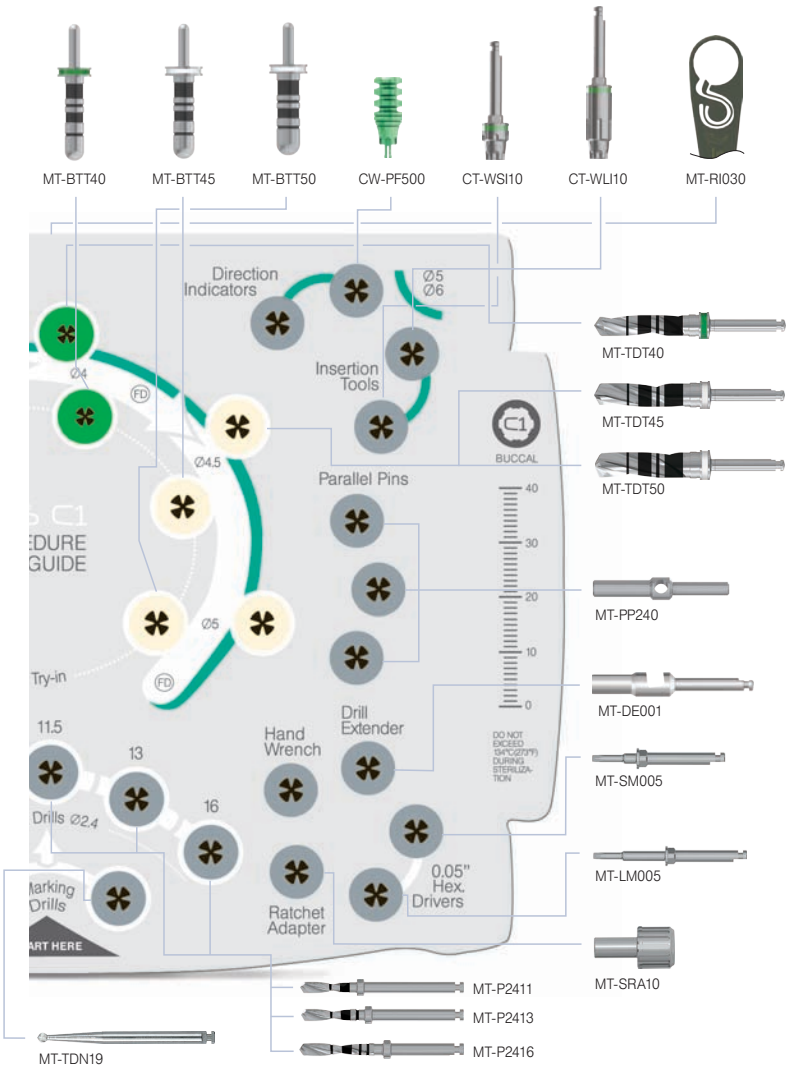
▪ Conduct a visual inspection of the instruments prior to each use. Do not use faulty or dull instruments. Clean and disinfect each instrument separately ▪ Do not allow traces/residue (blood, secretion, tissue residue) to dry on the instruments. Always soak in disinfecting fluid immediately after use ▪ Use only stainless steel dedicated detergents and strictly follow usage instructions ▪ Rinse instruments thoroughly with water to remove any remaining disinfectants or cleaning agents ▪ Do not store instruments that are damp or wet ▪ Use only nylon bristle brushes to clean instruments. Clean the cavities and hollow spaces thoroughly ▪ The use of an ultrasonic bath is highly recommended ▪ Do not clean/disinfect instruments made of different materials together ▪ To prevent damage, do not allow sharp instruments to touch other instruments during cleaning. ▪ After mechanical or manual cleaning, all surgical appliances must be sterilized in an autoclave, at 134˚C (273˚F) for a duration of 6 minutes. Do not exceed 134˚C. Never use dry sterilizers ▪ Inspect for corrosion after sterilization.

The Surgical Kit

Advanced Surgical Instrument Kit

MK-0044 | With external irrigation drills

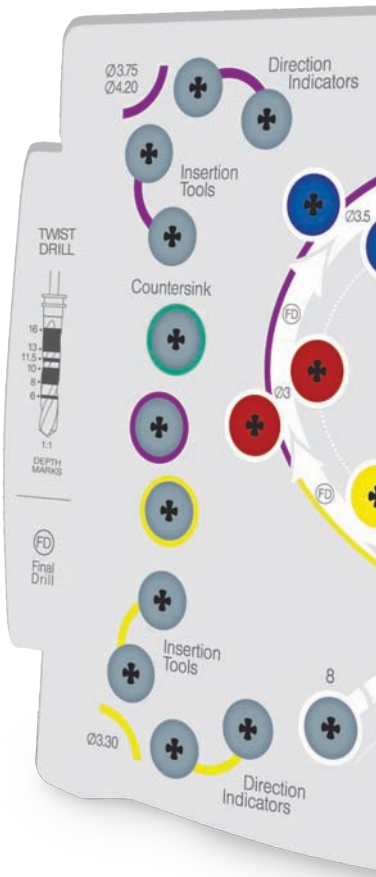


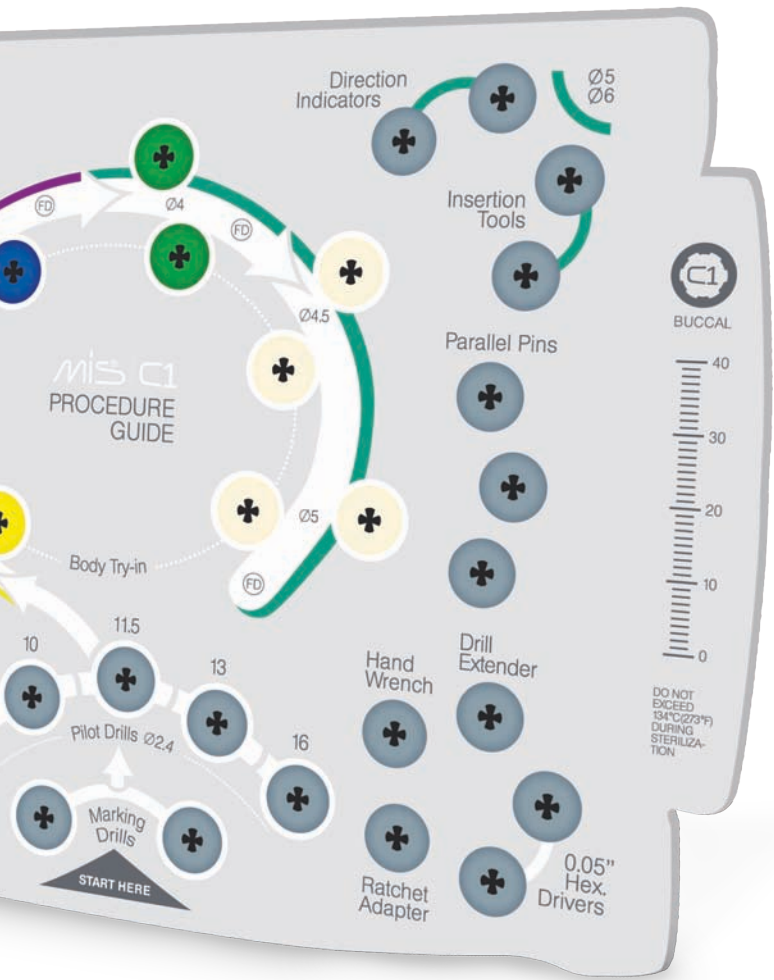

MT-BTT40
MT-BTT45
MT-BTT50
CW-PF500
CT-WSI10
CT-WLI10
MT-RI030
Direction Indicators
Ø5
Ø6
Insertion Tools
Parallel Pins
Ø4
Ø4.5
Ø5
FD
C1
BUCCAL
40
30
20
10
0
DO NOT EXCEED 134°C (273°F) DURING STERILIZATION
Try-in
Drill Extender
Hand Wrench
11.5
13
16
Drills Ø2.4
Marking Drills
Ratchet Adapter
0.05" Hex. Drivers
MT-TDT40
MT-TDT45
MT-TDT50
MT-PP240
MT-DE001
MT-SM005
MT-LM005
MT-SRA10
MT-P2411
MT-P2413
MT-P2416
MT-TDN19

The Surgical Kit

Kit Contents

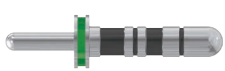
The C1 Surgical Kit includes tools that are designed especially for the step-by-step implant placement process. Correct preparation of the implant site ensures efficient and accurate installation and high primary stability.




Direction Indicators
Ø5
Ø6
Insertion Tools
Ø4
FD
FD
Ø4.5
mis c1
PROCEDURE GUIDE
Parallel Pins
Ø5
Body Try-in
FD
C1
BUCCAL
40
30
20
10
0
10
11.5
13
16
Pilot Drills Ø2.4
Hand Wrench
Drill Extender
Marking Drills
START HERE
Ratchet Adapter
0.05" Hex. Drivers
DO NOT EXCEED 134°C/273°F) DURING STERILIZA-TION

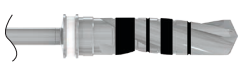
The Surgical Kit

Kit Contents

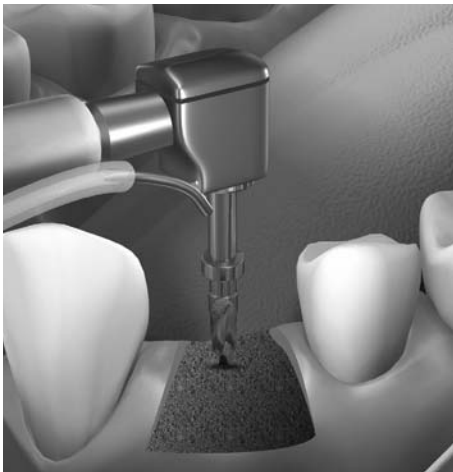
		Dimensions	Material
	MT-P2406 | Pilot drill with built in stopper Ø2.40 height 6mm	Ø2.40mm Length 31.8mm	Stainless steel
	MT-P2408 | Pilot drill with built in stopper Ø2.40 height 8mm	Ø2.40mm Length 31.8mm	Stainless steel
	MT-P2410 | Pilot drill with built in stopper Ø2.40 height 10mm	Ø2.40mm Length 31.8mm	Stainless steel
	MT-P2411 | Pilot drill with built in stopper Ø2.40 height 11.5mm	Ø2.40mm Length 31.8mm	Stainless steel
	MT-P2413 | Pilot drill with built in stopper Ø2.40 height 13mm	Ø2.40mm Length 31.8mm	Stainless steel
	MT-P2416 | Pilot drill with built in stopper Ø2.40 height 16mm	Ø2.40mm Length 31.8mm	Stainless steel
	MT-BTT24 | Body try-in Ø2.40mm for tapered impl. procedure	Ø2.40mm Length 28.5mm	Stainless steel
	MT-BTT28 | Body try-in Ø2.80mm for tapered impl. procedure	Ø2.80mm Length 28.5mm	Stainless steel
	MT-BTT32 | Body try-in Ø3.20mm for tapered impl. procedure	Ø3.20mm Length 28.5mm	Stainless steel
	**MT-BTT40** | Body try-in Ø4mm for tapered impl. procedure	Ø4mm Length 28.5mm	Stainless steel
	MT-BTT45 | Body try-in Ø4.50mm for tapered impl. procedure	Ø4.50mm Length 28.5mm	Stainless steel
	MT-BTT50 | Body try-in Ø5mm for tapered impl. procedure	Ø5mm Length 25.5mm	Stainless steel
	MT-TDN30 | Twist drill 3mm external irrigation	Ø3mm Length 37.6mm	Stainless steel

The Surgical Kit

Kit Contents

		Dimensions	Material
	MT-TDT32 | Twist drill 3.20mm external irrigation	Ø3.20mm Length 37.5mm	Stainless steel
	MT-TDT40 | Twist drill 4mm external irrigation	Ø4mm Length 38.2mm	Stainless steel
	MT-TDT45 | Twist drill 4.50mm external irrigation	Ø4.50mm Length 38.2mm	Stainless steel
	**MT-TDT50** | Twist drill 5mm external irrigation	Ø5mm Length 38.2mm	Stainless steel
	MT-SMD10 | Spade marking drill	Length 27.5mm	Stainless steel
	MT-TDN19 | Marking drill Ø1.90mm external irrigation	Ø1.90mm Length 34mm	Stainless steel
	MT-SRA10 | Square connection to ratchet adapter	Length 15.5mm	Stainless steel
	MT-LM005 | Long motor adapter for 0.05" hex.	Length 29mm	Stainless steel
	MT-SM005 | Short motor adapter for 0.05" hex.	Length 24mm	Stainless steel

		Dimensions	Material
	MT-DE001 | Drill extender	Length 28.85mm	Stainless steel
	MT-PP240 | Parallel pin Ø2.40mm for tapered impl. procedure	Ø2.40/ Ø3mm	Titanium
	CN-PF330 | Direct press fit for closed tray coni. con., NP	Length 16mm	Stainless steel
	CS-PF375 | Coni. con. direct press fit for closed tray, SP	Length 16.6mm	Stainless steel
	CW-PF500 | Coni. con. direct press fit for closed tray, WP	Length 16.6mm	Stainless steel
	CT-NSI10 | Coni. con. short insertion tool, NP	Length 22mm	Stainless steel
	CT-NLI10 | Coni. con. long insertion tool, NP	Length 30mm	Stainless steel
	CT-SSI10 | Coni. con. short insertion tool, SP	Length 22mm	Stainless steel
	CT-SLI10 | Coni. con. long insertion tool, SP	Length 30mm	Stainless steel
	CT-WSI10 | Coni. con. short insertion tool, WP	Length 22mm	Stainless steel
	CT-WLI10 | Coni. con. long insertion tool, WP	Length 30mm	Stainless steel
	MT-CSN33 | Countersink for Narrow platform implant system	Ø3.30mm Length 26mm	Stainless steel
	MT-GDN33 | Countersink for Standard platform implant system	Ø3.75mm/ Ø4.20mm Length 26mm	Stainless steel
	MT-GDN50 | Countersink for Wide platform implant system	Ø5mm/Ø6mm Length 26.8mm	Stainless steel



Drills.

48. Using MIS Drills
50. Color Code
52. Drilling Depth
54. Drill Indications
56. Final Drill
58. Drilling Into Hard Bone
59. Drill Cutting Capability
60. Ceramic Drills
61. Drill Maintenance

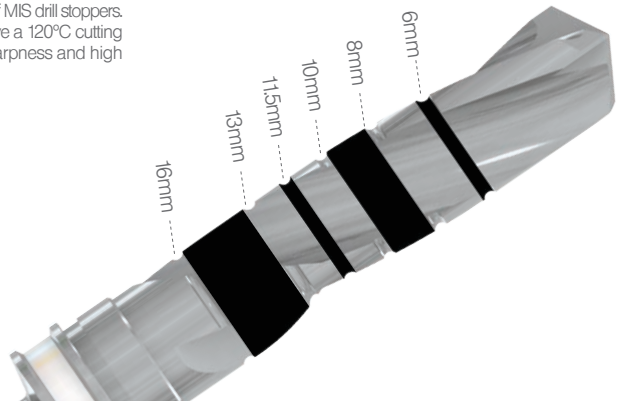
Drills

Using MIS Drills

Implant placement procedures require the use of several drills with different diameters and characteristics. MIS offers drills with internal and external irrigation, as well as conical and ceramic drills. Most MIS drills are marked for depth control and are color-coded for immediate identification of drill diameter.

Features

MIS drills are designed to be used with all MIS implants. Drills are available with or without internal irrigation. Short drills are also available for each diameter. All drills are color-coded. The drills are marked for depths of 6, 8, 10, 11.5, 13 and 16mm, and are equipped with a ledge that allows the connection of MIS drill stoppers. All MIS drills have a 120°C cutting degree. The sharpness and high quality of the drills allow for up to 30 uses. Careful use of sharp drills will ensure atraumatic drilling procedures, and minimal heat generation.



Drill Stoppers

MIS offers drill stoppers to enable simple and accurate depth control.

The C1 Drill Stopper Kits (MK-CDS08, MK-CDS10, MK-CDS11, MK-CDS13) are a series of kits, each used for one specific implant length: 8, 10, 11.5 or 13mm.

For commonly used 3.75 or 4.2 implants, MIS offers a single assorted kit - the C1 Drill Stoppers Kit Standard Platform (MK-BC101), which includes all stoppers required for safe placement of Standard platform implants.

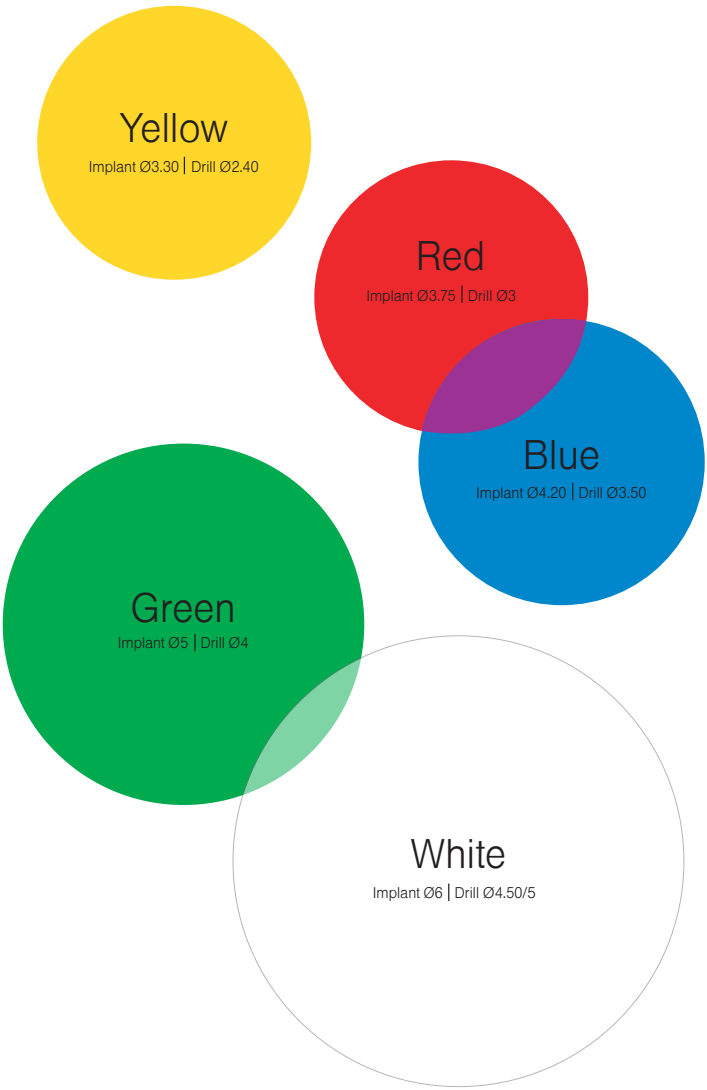
C1 Drill Stoppers Kit

C1 Drill Stoppers Kit
Standard Platform (MK-BC101)

	Implant	Length
	Ø3mm	37.6mm
	Ø3.50mm	37.7mm
	Ø4mm	38.2mm
	Ø4.50mm	38.2mm
	Ø5mm	38.2mm

Drills
Color Code

Color-coding is used for easy identification of drills or implants diameters as follows:



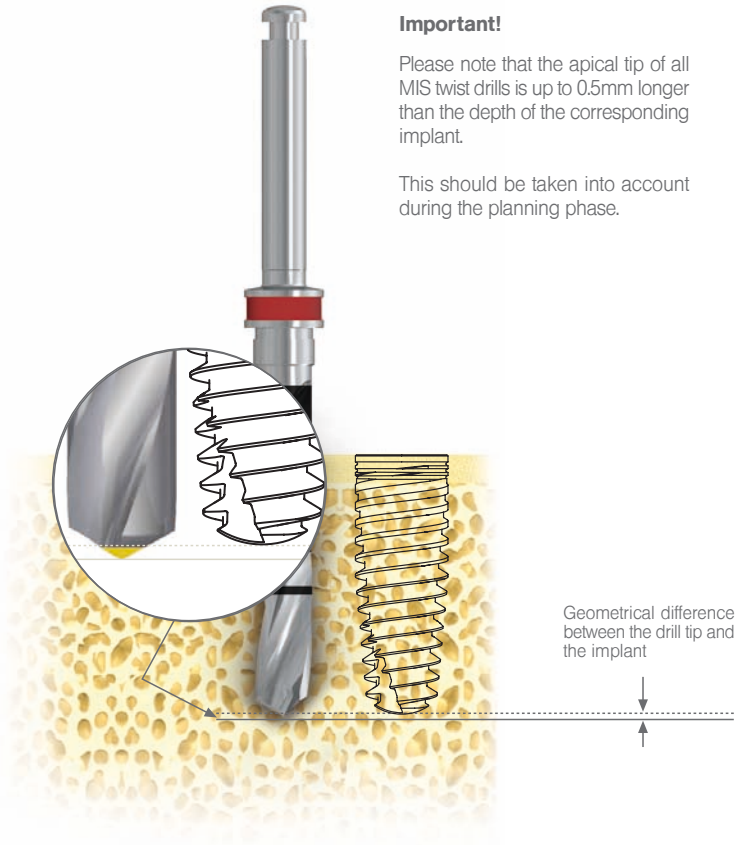
Drills

Drilling Depth

Important!

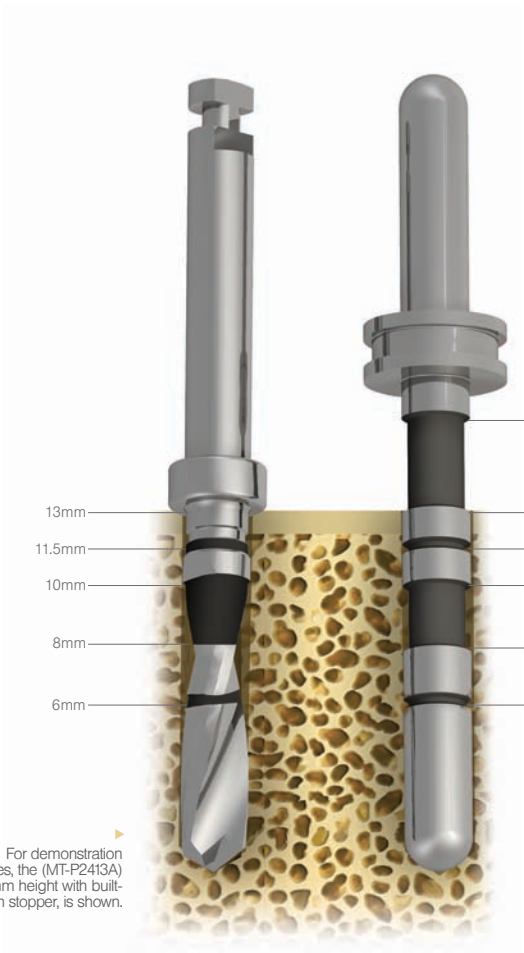
Please note that the apical tip of all MIS twist drills is up to 0.5mm longer than the depth of the corresponding implant.

This should be taken into account during the planning phase.



Depth Verification

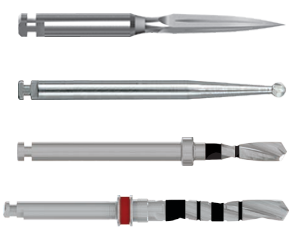
Depth verification can be done by the use of Body Try-In tools (MT-BTTx). Laser markings correspond to those on the drills and allow a safe, easy way to ensure that the required depth was achieved.

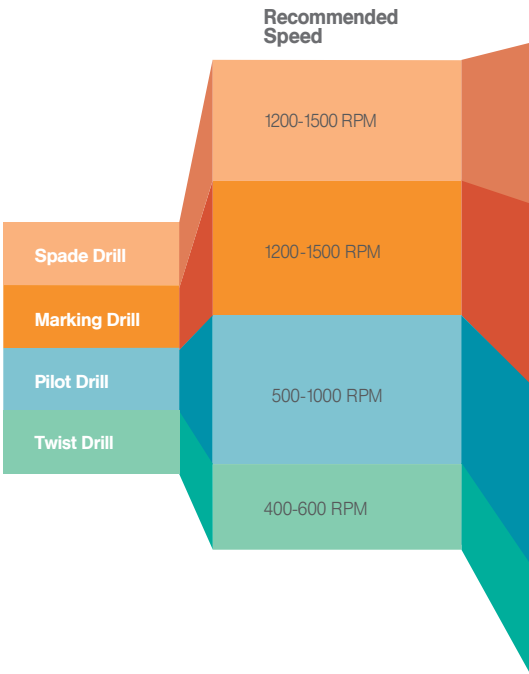


For demonstration purposes, the (MT-P2413A) drill, 13mm height with built-in stopper, is shown.

Drills

Drill Indications

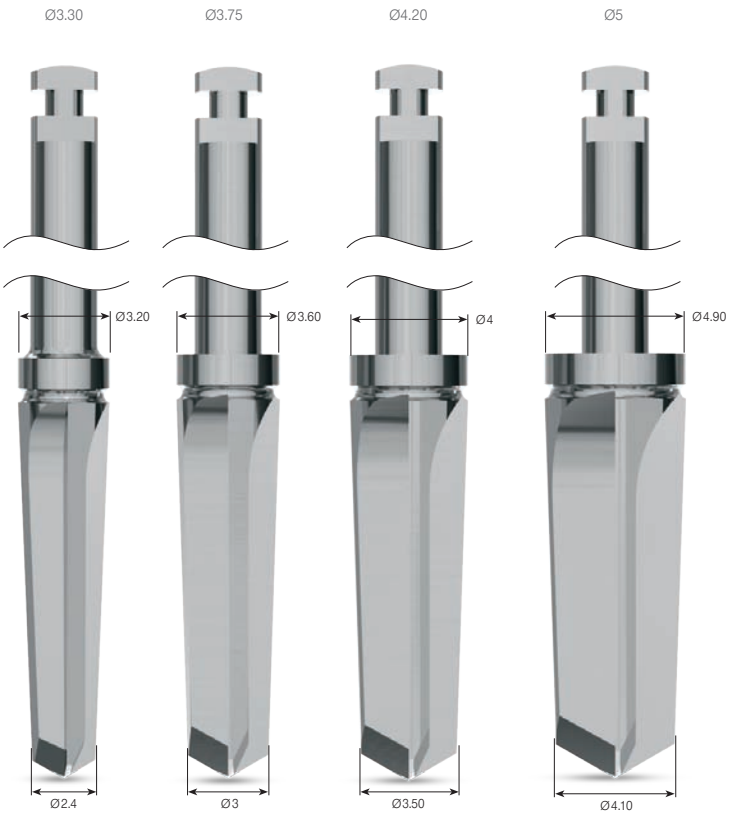




Length & Diameter	Aim of Use
The Spade Drill has a diameter of Ø1.9mm and a sharp tip. The Spade Drill is 27.5mm in length and made of stainless steel.	The Spade Drill is used to mark a reference point for further drills. It is especially useful in immediate placement procedures.
The Marking Drill supplied is 34mm in length and 1.90mm in diameter.	The Marking Drill is used for creating a reference point in the center of the ridge, and to mark the location for further drilling.
C1 Pilot Drills come in five different lengths: 8, 10, 11.5, 13 and 16mm and are equipped with a stopper to simplify the drilling procedure.	Pilot Drills are the first invasive drills used for the preparation of a fixture site. The Pilot Drills are length specific to ensure precise drilling depth.
Twist Drills come in a variety of diameters and lengths.	Twist Drills are used to widen the osteotomy. They are NOT length specific, and have laser markings for 6, 8, 10, 11.5, 13 and 16mm implants. The use of stoppers is highly recommended when using Twist Drills.

C1
Final Drill

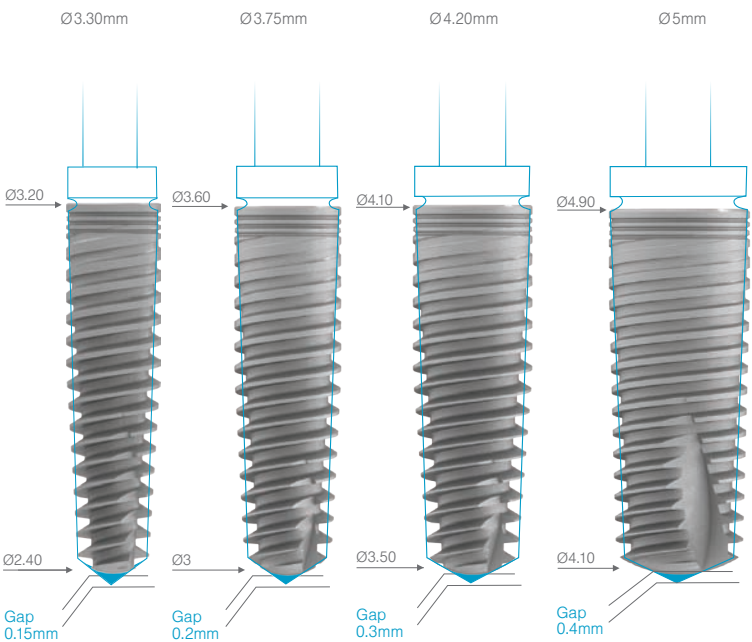
Final Drill for implant diameters



C1
Implant and Drill Measurements

Each C1 implant package contains a sterile, single-use Final Drill. The drills are recommended for use in bone types 1, 2 & 3. Each Final Drill has a predetermined length and diameter, matching the relevant implant shape and dimension ensuring maximum initial stability while preventing pressure on the implant neck. The length-specific final drills also promote a short and safe drilling procedure. The recommended drilling speed is 200-400 Rpm.

Implant and drill measurements



Drills

Countersink Drills

When drilling into hard bone, extra care should be exercised to prevent overheating. Therefore, lower speeds and higher torque should be used. In addition, to prevent extensive pressure on the bone or the need of extremely high insertion torque, it is highly recommended to use the appropriate countersink drills at the end of the drilling procedure.

Countersink Drills (MT-CSN33, MT-GDN33, MT-GDN50)

Countersink Drills are used to enlarge the crestal area of the implant site, preventing excessive pressure on the implant neck. Depth marks of 3.30 appear on the Narrow platform Countersink Drill (MT-CSN33), 3.75 and 4.20mm marks appear on the Standard platform Countersink Drill (MT-GDN33), 5 and 6mm marks appear on the Wide platform Countersink Drill (MT-GDN50). The recommended drilling speed is 200-500 RPM. When drilling into hard bone, extra care should be exercised to prevent overheating. Therefore, it is recommended to use lower drilling speeds with higher torque. In addition, to prevent excessive pressure on the bone or the need for extremely high insertion torque, it is strongly recommended to use the appropriate countersink drills upon completion of the drilling procedure.

Drills

Ceramic Drills

Ceramic Drills feature reduced vibration, smooth operation and continuous substance removal.

MIS Ceramic Drills are made from a high performance mixture of zirconium dioxide (zirconia) and aluminum oxide (alumina) ceramics. The mixture of these two materials provides an above-average bending strength of 2,000 MPa. In comparison, the bending strength of zirconium oxide ceramic, used in the manufacturing of root posts is 1,200 Mpa.

Advantages: Metal-free, biocompatible, corrosion-free

MT-CRD21
Marking Drill

Dimensions: Ø2.10mm Length 28.5mm

Material: Zirconia-alumina ceramic

MT-CRD20
Pilot Drill

Dimensions: Ø2mm Length 33.5mm

Material: Zirconia-alumina ceramic

MT-CRD28
Twist Drill

Dimensions: Ø2.80mm Length 35mm

Material: Zirconia-alumina ceramic

Drills

Drills Maintenance

Correct and careful maintenance of MIS drills is extremely important. Damage to drill tips can cause significant impairment of drill function. The following are detailed instructions for proper maintenance.

Instructions for Maintenance of Drills Prior to First Use

Stage 1: Cleaning and Rinsing - Drills should be dipped in appropriate detergent, rinsed, and dried. The use of an ultasonic bath is highly recommended.

Stage 2: Sterilization - Drills should be sterilized in an autoclave at 134˚C (273˚F) for 6 minutes. Do not exceed 134°C.

Stage 3: During Use - Drills should be soaked in a sterile saline solution until the cleaning stage.

Instructions for Cleaning and Storage of Drills After Use

Stage 1: Cleaning - Drills should be brushed with detergent to remove any remaining blood or tissue.

Stage 2: Ultrasonic cleaning - Drills should be cleaned in an ultrasonic bath with appropriate detergent. Note: during ultrasonic cleaning, contact between drills should be avoided.

Stage 3: Rinsing - Drills should be rinsed under running water and dried.

Stage 4: Sterilization - Drills should be sterilized in an autoclave at 134˚C (273˚F) for 6 minutes. Do not exceed 134°C.

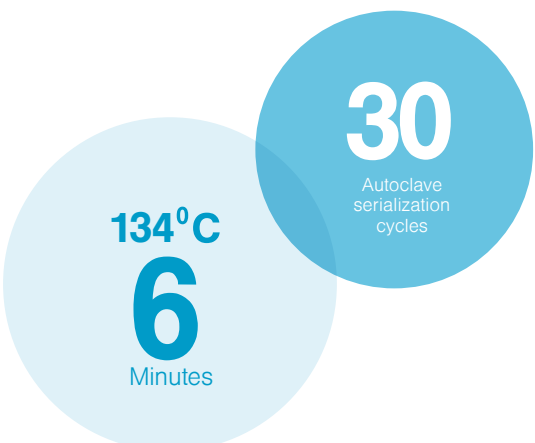
Stage 5: Storage/Use - Store kits in a cool and controlled environment. Please note that sterilization may expire after a certain time. If kits have been stored for a prolonged period, resterilize them prior to use.

Drills

Drills Maintenance

Recommendations

- Cutting tools should be used for a maximum of 30 uses.
- Distilled water should be used in order to avoid surface stains.
- 134°C (273°F) for 6 minutes: Autoclave for Instruments/drills/kits



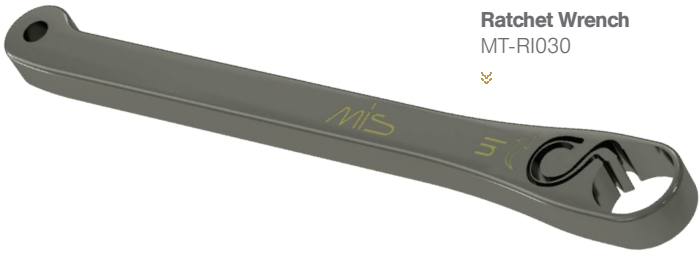
Surgical & Prosthetic Tools.

64. Specialized Surgical Tools
72. Specialized Prosthetic Tools
76. Screw Tests
77. Maintenance

Ratchet

Mono-Block Ratchet Wrench

The new ratchet is a mono-block instrument with a unique mechanism that simplifies use and cleaning. To prevent damage to the mechanism, it is critical that the ratchet is used only with keys and adapters that are specifically designed for it. The ratchet wrench can be used for implant placement and tightening or loosening screws.



Ratchet Wrench
MT-RI030

Warnings

It should be emphasised that MIS recommends the use of a torque controlled driver whenever possible.

The Ratchet Wrench MT-RI030 may transfer torque levels that do not correlate to the recommendations specified for implant placement or screw fastening.

Excess loads may result in damage to implants, components, screws, the wrench itself and even to the bone-to-implant interface.

Instrument Maintenance

- The device is not sterile.
- Cleaning and sterilization are required prior to first use.
- Clean instrument with running water to remove any blood or tissue immediately after use.

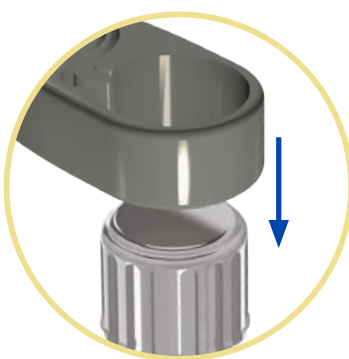
Cleaning and Disinfection:

- Immerse instrument in an approved cleaning/disinfecting solution.
- Use of an ultrasonic cleaner is highly recommended.
- DO NOT USE agents containing high cocentration of chlorine or agents containing oxalic acid.
- Use distilled water to prevent water stains.

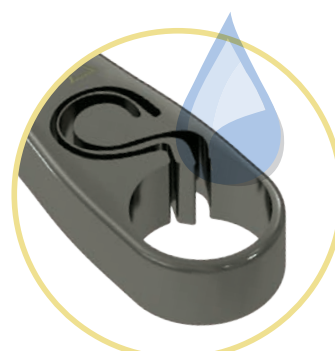
Sterilization

- All dental instruments must be sterilized prior to each use.
- The device is delivered non-sterile.
- Before use, the device must be sterilized by autoclave at 134°C (273°F) for 6 minutes. Do not exceed 134°C.

User Instructions



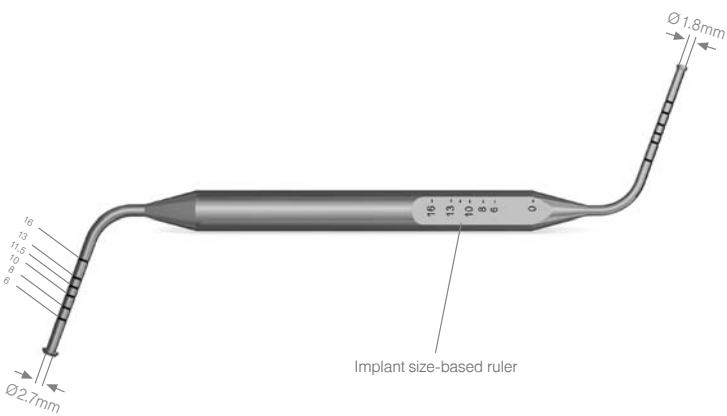
Store the ratchet on its own, not attached to any tools.



Clean thoroughly immediately after use.

Surgical Tools
Specialized Surgical Tools

Implant Site Depth Probe
MT-BTI10



Features

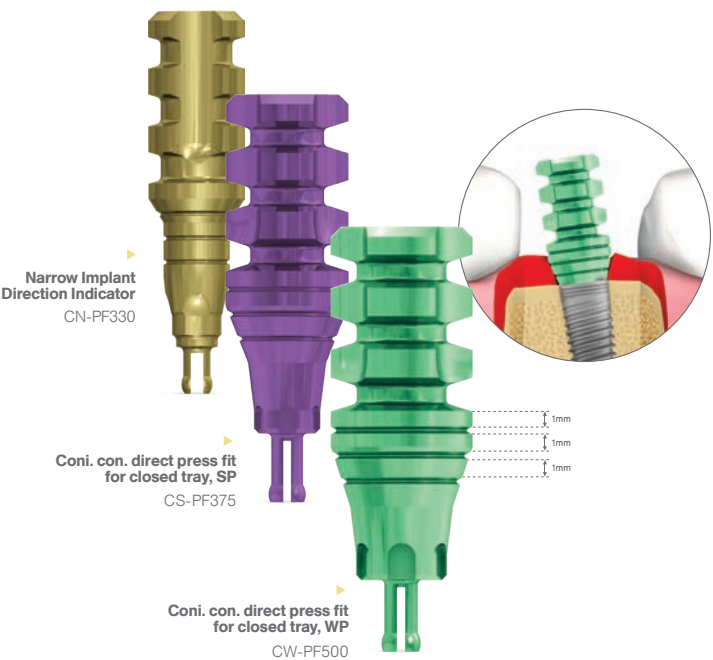
The Depth Probe enables quick and easy measurements and examination of a prepared implant site, at each step of the procedure.

Marked depths: 6, 8, 10, 11.5, 13 and 16mm. The Depth Probe includes an apical flat section to ensure accurate placement within the osseotomy.

Dimensions: Ø 1.80/Ø 2.70mm. Total length:100mm.

Implant Direction Indicator CT-SDI01

Connected directly to the implant, this surgical instrument enables the visualization of the 3D position of a particular implant. The implant indicator features groove marks indicating gingival heights (each groove mark indicates 1mm of gingival height). The round cavities at the upper section of the tool represent the position of the anti-rotational index within the implant.



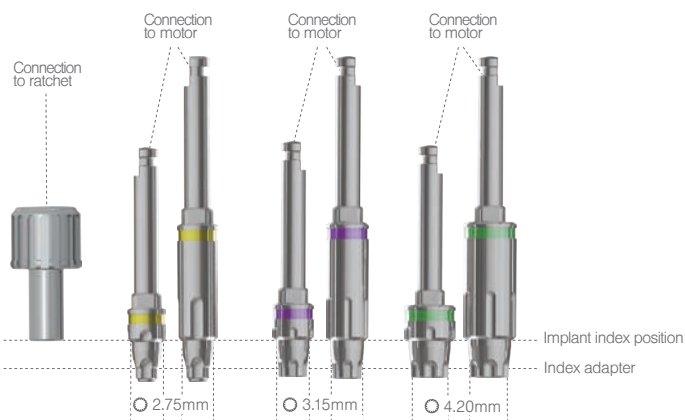
Surgical Tools

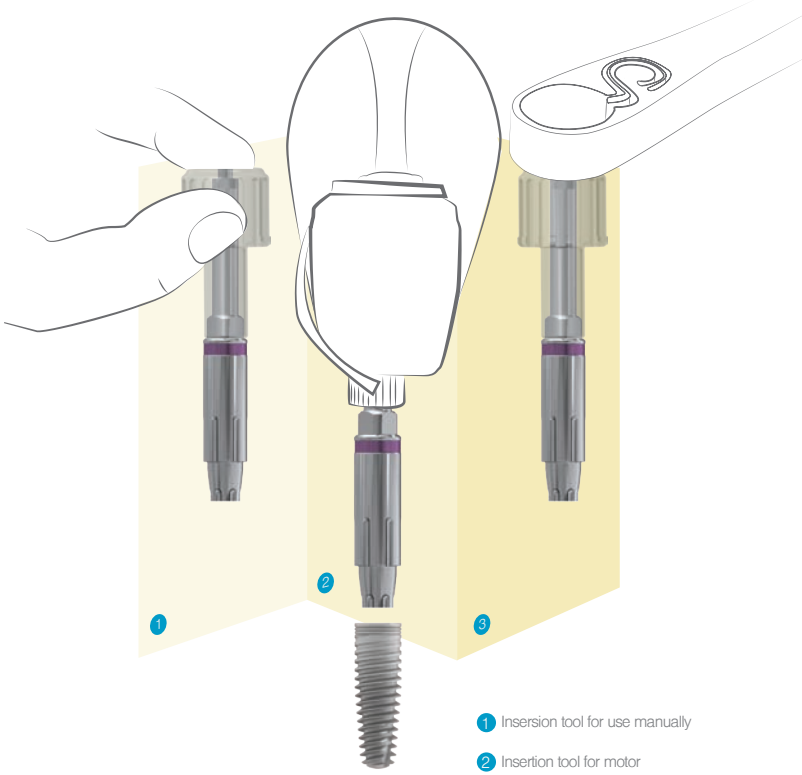
Specialized Surgical Tools

C1 Insertion Tools

C1 implants are divided into Narrow platform implants (3.30mm), Standard platform implants (3.75 and 4.20mm), and Wide platform implants (5mm). Long and short insertion tools are available for each of the C1 platforms.

In order to simplify procedures, the 3-in-1 concept was developed. This concept is based on the ability of one insertion tool to be used either directly in a motor, with a manual wrench or with any of the MIS ratchets.





1. Insersion tool for use manually
2. Insertion tool for motor
3. Insertion tool for use with Ratchet wrench

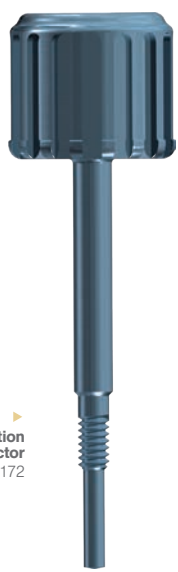
The same procedure is applicable for Wide platform tools.

Prosthetic Tools

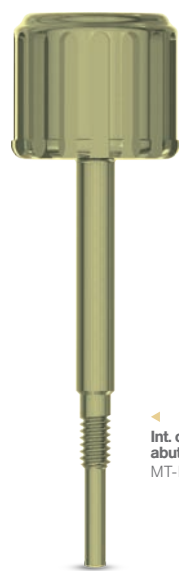
Specialized Prosthetic Tools

Friction Fit
MT-RE172/ MT-RE160

The friction fit extractors are designed to separate the friction fit abutments from the implant. The extractors are color-coded, Blue for Standard/Wide abutments and Yellow for Narrow abutments.



Int. connection abutment extractor
MT-RE172

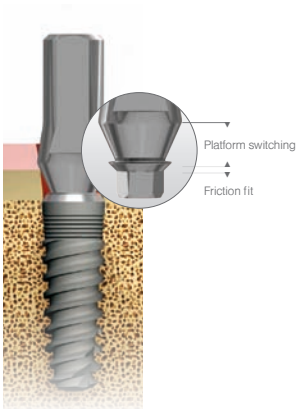


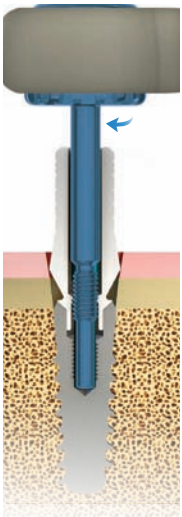
Int. connection abutment extractor, NP
MT-RE160

Mode of action

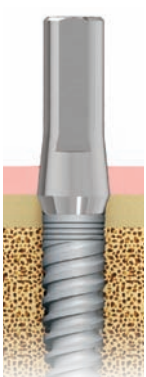
The extractor key applies vertical load parallel to the long axis of the implant. Thus it can release a "locked" abutment from an implant.

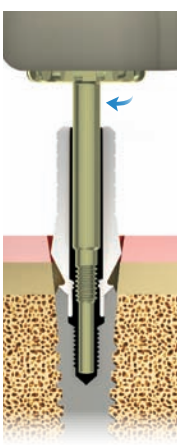
For Standard / Wide Implants





For Narrow Implants





Prosthetic Tools

SOS Broken Screw Kit

SOS Broken Screw Kit
MT-TF172 / MT-RT001/ MT-HW001

The SOS Broken Screw Kit was designed to facilitate the removal of a broken screw from within an implant.

SOS Broken Screw Kit
MK-0041

SOS Tools

Thread Former
MT-TF172

Retriever
MT-RT001

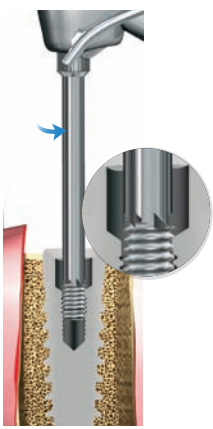
Hand Wrench
MT-HW001

Instructions for use:

1.

A. Connect the retriever to a micromotor.

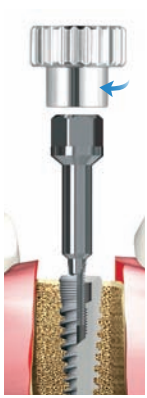
B. Adjust the micromotor to low speed (15-25 RPM), max. torque and in reverse mode.



2.

A. Apply mild pressure with the retriever at the top of the broken screw.

B. While maintaining pressure, activate the motor. This action should release the screw. If the screw is still not released, apply intermittent pressure on the screw.



3.

If internal threads are damaged:

A. Use the thread former with care.

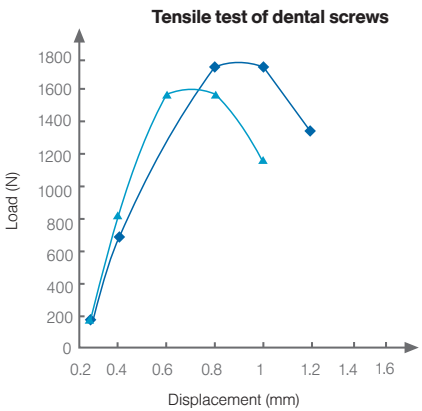
B. Be sure to align the thread former parallel to the long axis of the implant.

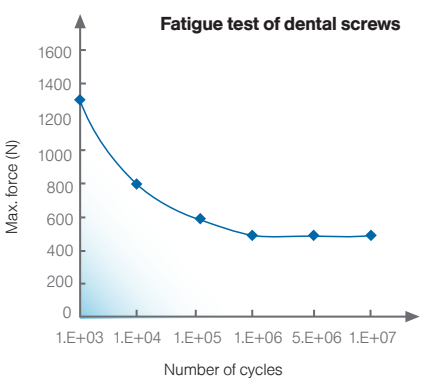
C. Always start by using a hand wrench. Apply gentle but firm force while turning the thread former in a clockwise direction. Release the pressure at the end of each complete turn by turning it 30' in a reverse direction, and repeat the action as needed.

D. In instances where greater torque is needed, a ratchet may be used.

Prosthetic tools

Screw Tests





Test conditions:

20 Ti-6Al-4V ELI, M2 type screws.
Loading frequency: 30Hz

Test results indicate that the fatigue limit of the tested screws is 530N and that the screws will not break even after 5 million cycles.

Maintenance

The wide variety of MIS surgical tools requires careful maintenance:

Instrument maintenance:

MIS surgical instruments are delivered non-sterile, unless indicated otherwise.

Disinfection

- Immerse instruments immediately after use.
- Use approved agents only.
- Observe manufacturer's recommendations regarding concentration/time/material compatibility.
- Verify that detergents and cleaning agents do not contain oxalic acid or high rates of chlorine.
- Avoid extremely high temperatures during cleaning and sterilization of the product.

Cleaning

- Remove all residues.
- Use an ultrasonic bath.
- Use anticorrosive cleaning agent.
- Thoroughly rinse away cleaning and disinfecting agents with running water.
- Use distilled water to prevent water spots.

Drying

Allow instruments to dry prior to sterilization.

Examination

- Perform a visual inspection.
- Dispose of damaged instruments.

Check for:
Broken or dull drill blades
Bent instruments
Corrosion

Sterilization

Surgical instruments must be sterilized before use by autoclave, at 134°C (273°F) for 6 minutes. Do not exceed 134°C.

Storage

Store in a dry, dust-proof area. Keep instruments separated from chemicals. Resterilize prior to use, if instruments have been stored for a prolonged period of time.

Packaging.

80. Implant Package
82. Implant Identification Codes
83. Implant Data Label
84. Implant Package Handling

Packaging

Implant Package

The innovative MIS packaging system is designed for simple and easy use. All of our implant boxes feature distinctive colors, large typeface, clear data labels and a pull tab for quick opening. Boxes are a uniform shape and height, specifically designed to fit in clinic cabinets for easy accessibility and compact space-saving storage.

Implant package

The Individual Implant Package

Each C1 package contains: Instruction For Use, an implant, a single-use final drill, a cover screw and a PEEK temporary cylinder. We recommend instructions be read carefully prior to use.

Insertion of the adapter

10 Implant Package

A convenient 10-implant package is available. The drawer-like box is ideal for storage in drawers or cabinets for easy identification of implant type, diameter and length.

Cover screw

Implant

Double Container System

To ensure that implants are sterile, and to prevent surface contamination, each implant is stored in a Titanium sleeve within an internal plastic tube. This tube is held in a larger sealed outer tube, marked with all relevant information. The inner tube is therefore sterile, and can be brought into the sterile surgical field whenever needed.

Packaging

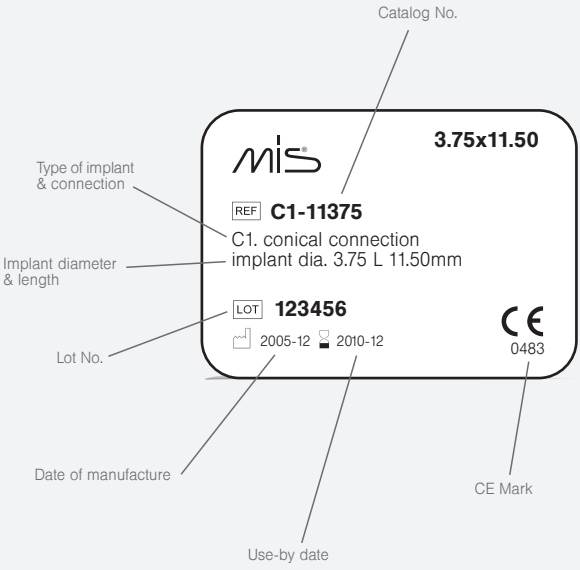
Implant Identification Codes

Identification markings on the outer tube cap enable quick identification of implant diameter (top), implant length (center) and implant platform size (bottom).

Packaging

Implant Data Label

Each package contains three data labels, which includes all required information pertaining to the implant. The following image illustrates the label:



Packaging

Implant Package Handling

The distinctive blue C1 implant boxes are a uniform shape and height, specifically designed to fit in clinic cabinets for easy accessibility and compact space-saving storage.

Fig. 1

The convenient pull tab facilitates easy, quick opening of the box during surgery.

Packaging

Implant Package Handling

Fig. 2

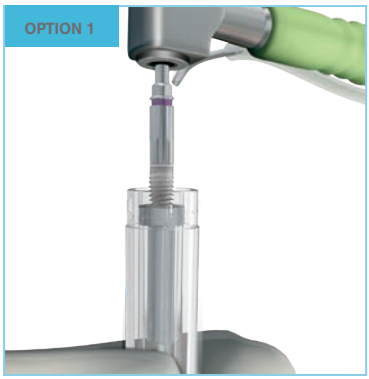
Open the outer tube by turning the cap counter-clockwise. Drop the sterile inner tube into the sterile field.

Fig. 3

The implant is held by the titanium sleeve. To expose the implant - hold the tube with the titanium sleeve facing up. Rotate and pull to open the upper cap.

Packaging

Implant Package Handling



Use one of the following options to remove the implant from the inner tube:

Fig. 4
Contra-angle hand piece

Fig. 4B
Hand wrench

Packaging

Implant Package Handling

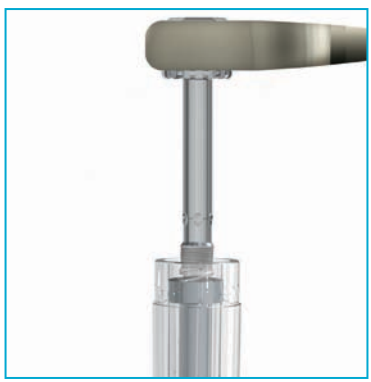


Fig. 5
Ratchet

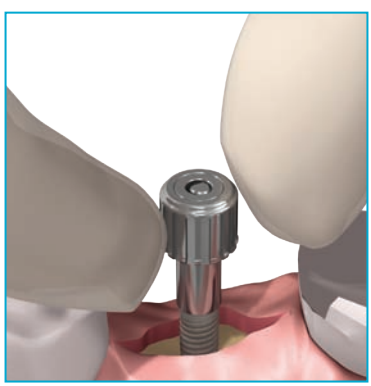


Fig. 6
Implant placement (illustrated using a manual wrench)

Packaging

Implant Package Handling

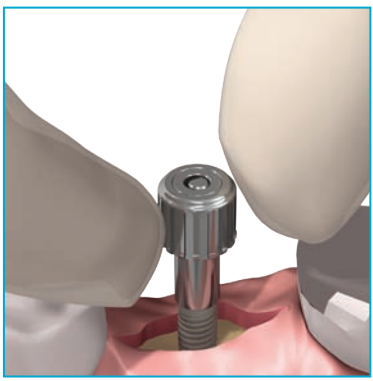


Fig. 4

Implantation procedure

Fig. 8

Open the bottom of the inner tube. Remove the cover screw using the MT-LM005 key

Packaging

Implant Package Handling

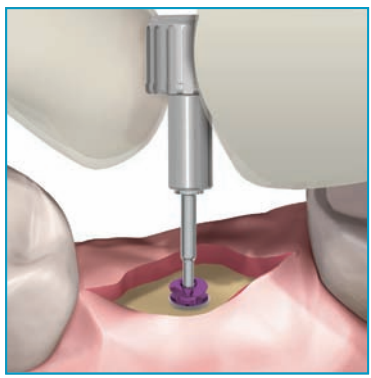


Fig. 9

Attach the cover screw to the implant using the MT-LM005 key

Fig. 9

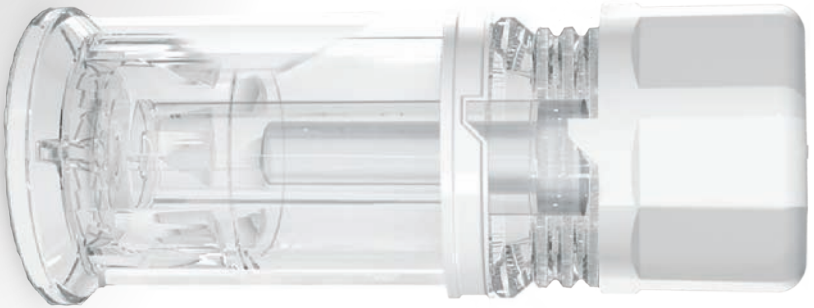
The data labels should be attached to the medical chart

Packaging

Implant Package Handling

Final Drill

Inner Tube



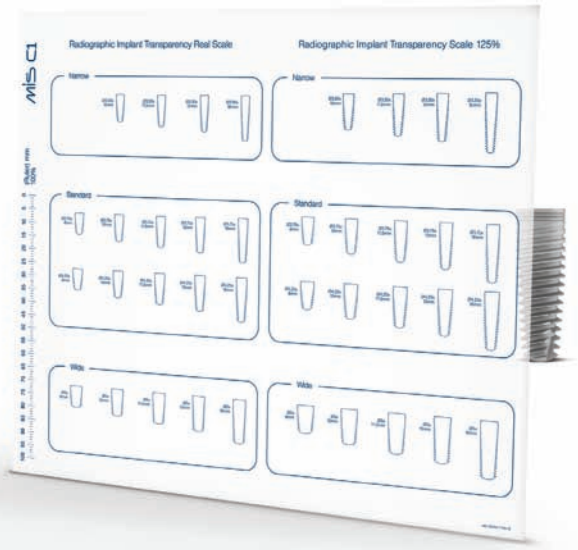
Outer Tube

Planning Transparency

MIS offers a planning transparency, illustrating the full C1 implant range. It includes two sets of images: one actual size, and the other at a magnification of 125%, relevant for use with panoramic radiographs that include a similar inherent magnification. In addition, the transparency includes a 1:1 ruler.

By placing the appropriate section of the transparency on a radiograph, a clinician can choose the best fitting implant diameter and length, as part of the planning process.

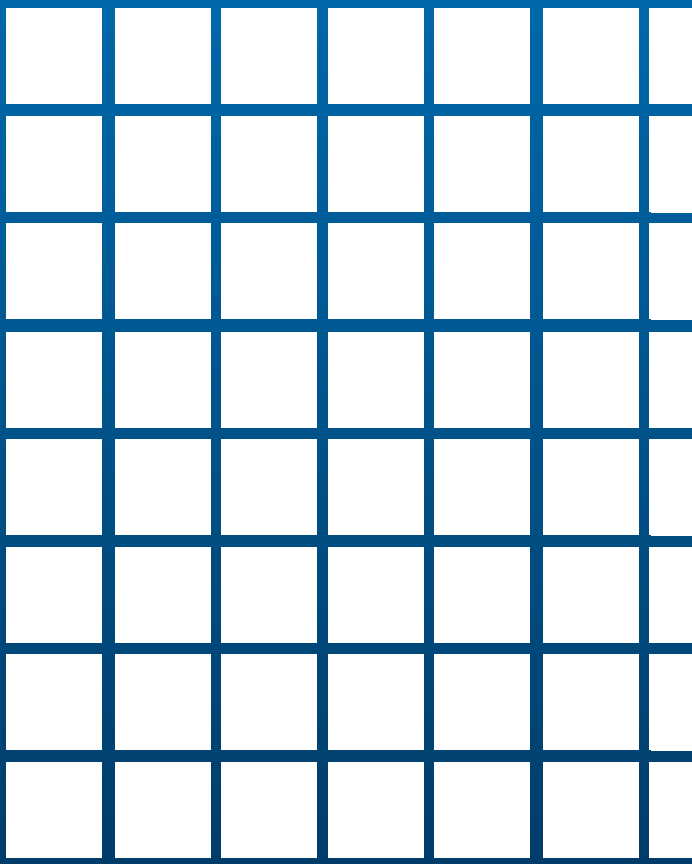
The transparency available for C1 implants is: Cat No. **MC-CONC1**

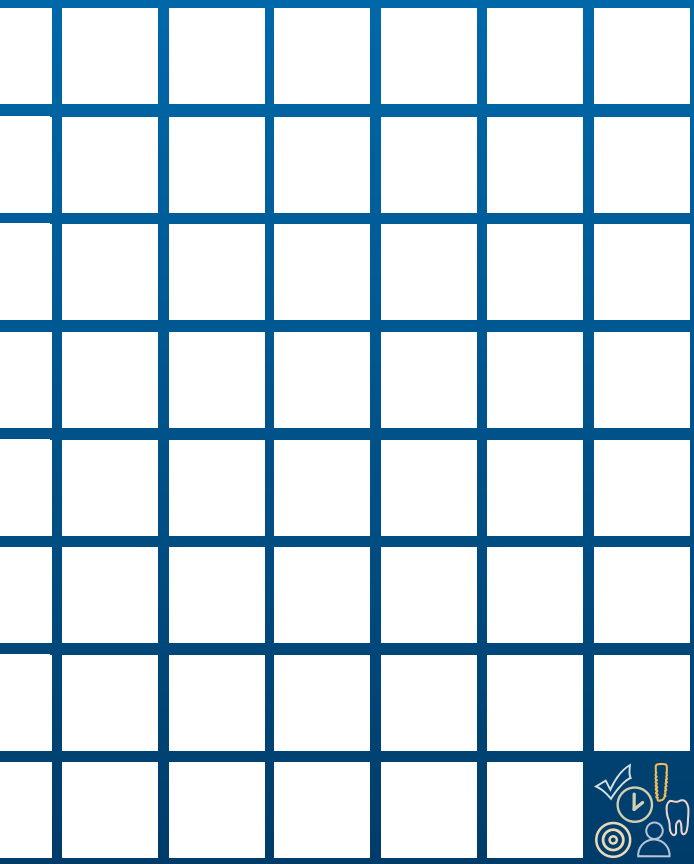


Symbols

Key to symbols on labels and instruction leaflets:

LOT Batch code	Manufacturer
REF Catalog number	Do not resterilize
For single use only	Do not use if package is damaged
Attention, see instructions for use	EC REP Authorised representative in the European community
Date of manufacture	Use-by date
STERILE R Sterilized using gamma irradiation	





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MP-UMCSE Rev.2 Apr 2015

MIS Implants Technologies Ltd.
www.mis-implants.com

MIS Quality System complies with international quality standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 – Quality Management System and CE Directive for Medical Devices 93/42/EEC. MIS products are cleared for marketing in the USA and CE approved.